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(54) Tissue dissector apparatus

(57) Surgical apparatus and method includes a cannula that houses an endoscope and supports a dilating element near a distal end of the cannula. The dilating element has a dimension which is greater than the diameter of the cannula for enlarging a surgical cavity in tissue as the cannula is advanced through tissue at a surgical site to provide working space adjacent a target vessel within which surgical instruments may be conveniently manipulated. The dilating element of oval sided shape permits surrounding tissue to be pushed away or otherwise displaced away from the target vessel atraumatically. A locking mechanism is disposed on

the cannula, which accepts a succession of mating dilating elements of progressively larger dimensions for successive insertion and enlargement of a surgical cavity as required. In one embodiment, the dilating element is made of rigid plastic, and in another embodiment, the dilating element is made of resilient material that may be confined within a retractable sheath which, in the extended position, encases and compresses the dilating element to a smaller dimension and which, in a retracted position, allows the dilating element to resiliently expand and enlarge the surgical cavity.

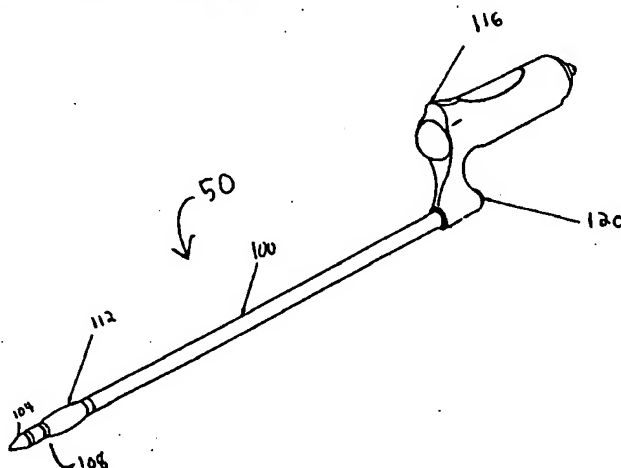


Figure 1

EP 0 979 635 A2

Field of the Invention

[0001] The present invention relates to the field of surgical apparatus, and more particularly to endoscopic vessel isolators.

Background of the Invention

[0002] During surgical harvesting of vessels, a target vessel is exposed, tributaries are ligated and transected, and the vessel is harvested. In order to view the vessel, a cannula housing an endoscope is inserted into a surgical cavity to visualize the adventitial layer of a target vessel. The vessel is tacked by advancing the cannula along the path of the vessel while bluntly dissecting the cavity as the cannula is advanced. Upon viewing a side branch or tributary of the vessel, a surgical tool is inserted into the surgical cavity to cauterize and sever the side branch. The endoscope remains in the surgical cavity during this process to allow the surgeon to view the procedure, and the size of the cavity is maintained using insufflating gas. Using different tools simultaneously in a surgical cavity is difficult due to the small size of the surgical cavity. Additionally, within the surgical cavity, the surrounding tissue typically collapses upon the cannula and surgical tools, increasing the difficulty of the operation, if performed without insufflation. However, maintaining the surgical cavity open using insufflation with gas under pressure then also requires sliding gas-tight seals for each endoscopic instrument that is inserted into the surgical cavity.

[0003] Current systems commonly employ a balloon coupled to the cannula for intermittent inflation and deflation to enlarge the surgical cavity as the cannula is advanced. However, use of a balloon to enlarge surgical cavities has the disadvantage that multiple balloon inflation and deflation tires the surgeon's hands, and makes it difficult to retain the precise hand control needed to perform the surgical procedure. Also, manufacture of a balloon cannula requires manual mounting of the balloon in a tedious process that adds expense to the device. Additionally, balloons have a potential for rupture during use and thereby disrupt the surgical procedure. Thus, a device is needed which retains the endoscopic vessel tracking ability of current systems, while also enlarging the surgical cavity without the disadvantages of balloon systems.

Summary of the Invention

[0004] In accordance with the present invention, a tissue dissector is provided in which a cannula houses an endoscope, and a dilating element is coupled near the distal end of the cannula. The dilating element has an outer dimension which is greater than the diameter of the distal end of the cannula. This greater dimension

serves to enlarge the surgical cavity as the cannula is advanced through the surgical site, thus allowing the cannula to track along the vessel while forming a working cavity and providing room within which additional surgical tools may operate safely. In one embodiment, the dilating element is in the shape of an oval, allowing compression of the surrounding tissue to occur atraumatically.

[0005] In an alternate embodiment, a locking mechanism is disposed on the cannula, and the dilating element is coupled to the locking mechanism when enlargement of the surgical cavity is required. In this embodiment, multiple dilating elements of differing outer dimensions may be employed responsive to the enlargement required. Various locking mechanisms may be employed in accordance with the current invention, including using screw threads disposed on the surface of the cannula, and mating internal screw threads in a bore hole through the dilating element to permit the dilating element to couple to the screw threads. Alternatively, the dilating element may include a bayonet-type fitting, with mating knobs on the associated surface portion of the cannula for locking the dilating element into place. Additionally, in one embodiment the tip and dilating element are a single detachable component, and may be coupled and decoupled to the main body of the cannula as desired. This greatly facilitates use of dilating elements of different dimensions.

[0006] The body of the cannula may be tapered from a smaller diameter near the distal end of the cannula to a larger diameter remote from the distal end of the cannula. The tip of the cannula is transparent to facilitate endoscopic viewing of the surgical cavity. The tapering of the distal end of the cannula may begin at a point forward of the distal end of the dilating element. This allows the tip of the cannula to track along the target vessel without the enlarged diameter of the dilating element preventing the tip from making contact with the target vessel. In one embodiment, the dilating element is made of rigid plastic to facilitate expansion of a working cavity and ease of translation through the surgical site. In another embodiment, the dilating element is made of a flexible material which compresses as the external walls exert force upon the cannula, but retains sufficient structural rigidity to accomplish the required enlargement of a working cavity. In yet another embodiment, the dilating element is made of flexible material and is shrouded within a retractable sheath which, in the extended position, encases the dilating element and thereby compresses the dilating element to a smaller diameter, and in a retracted position, allows the dilating element to expand and enlarge the working cavity.

[0007] Methods are also disclosed for dissecting an elongated cavity along the course of a vessel using a cannula according to one or other embodiments of the present invention, including incising the skin of a patient, placing the tip of the cannula along the surface of the vessel, advancing the cannula along the vessel

under continuous endoscopic visualization through the tip, enlarging the cavity about the outer dimension of the dilating element, removing the cannula upon reaching the desired length of target vessel, and optionally placing a sealing trocar in the incision and maintaining the enlargement by insufflating the subcutaneous tunnel with gas under pressure. The vessel may then be harvested through a separate incision near the remote end of the surgical cavity.

Brief Description of the Drawings

[0008]

Figure 1 illustrates a perspective view of the cannula in accordance with one embodiment of the present invention.

Figure 2 is a cut-away side sectional view of the cannula in accordance with the present invention.

Figure 3 is a perspective view of the distal end of cannula in accordance with the present invention.

Figure 4 is a flow chart illustrating the application of cannula in accordance with the present invention.

Figure 5a illustrates a cannula having a locking mechanism in accordance with one embodiment of the present invention.

Figure 5b is a side view of a dilating element for locking attachment to the cannula in Figure 5a.

Figure 5c is a cut-away side sectional view of the dilating element for use with the cannula of Figure 5a.

Figure 6a is a cannula having an alternate embodiment of a locking mechanism in accordance with the present invention.

Figure 6b is a side view of a dilating element for locking attachment to the cannula of Figure 6a.

Figure 6c is a cut-away side sectional view of the dilating element for use with the cannula of Figure 6a.

Figure 7 is an exploded view illustrating the removable module of tip and dilating element on a cannula in accordance with another embodiment of the present invention.

Figure 8 is a flow chart illustrating the operation of the interchangeable dilating element embodiment of the cannula in accordance with the present invention.

Figure 9a is a cut-away side sectional view of an embodiment of the present invention including a retractable sheath illustrated in extended position.

Figure 9b is a cut-away side sectional view of the embodiment of Figure 9a with the retractable sheath illustrated in retracted position.

Figure 10 is a flow chart illustrating the operation of the retractable sheath embodiment of the cannula in accordance with the present invention.

Detailed Description of the Invention

[0009] Figure 1 illustrates a tissue dissector 50 in which a cannula 100 is coupled to a dilating element 112. The proximal end of cannula 100 is coupled to a handle 116 and the distal end of cannula 100 is enclosed by transparent tapered tip 104. Dilating element 112 is positioned inwardly from the distal end of the cannula 100. Cannula 100 may be made from a variety or combination of bioinert, substantially inelastic materials, such as stainless steel, polyethylene, polyurethane, polyvinyl chloride, polyimide plastic, and the like that preferably have a tensile strength of at least 10,000 psi. Handle 116 is ergonomically formed to allow a surgeon to easily and comfortably manipulate cannula 100 within a surgical cavity.

[0010] Figure 2 illustrates a cut-away side sectional view of tissue detector 50. As shown, the distal end of cannula 100 has an outer diameter or dimension 136, and the dilating element 112 has an outer dimension 132 which is greater than the diameter 136. The proximal portion of cannula 100 preferably has a smaller dimension than the dilating element 112 to allow more flexibility in maneuvering the cannula 100 in the surgical site. The greater dimension 132 of dilating element 112 enlarges or expands a surgical cavity by pushing away surrounding tissue within a surgical cavity as the cannula 100 is advanced through a surgical site. The surgical cavity may thus be formed adjacent to a target vessel as a result of the blunt tissue dissection caused by the tapered tip 104 as it is advanced along the path of a target vessel, such as the saphenous vein. A preferable diameter 136 of cannula 100 is about 8.5 mm, and preferable outer dimensions 132 of dilating elements 112 are in the range from about 15 mm to about 30 mm. Thus, in application, a surgical cavity is initially formed by the tapered tip 104, and is initially increased or enlarged to the diameter 136 of the distal end of cannula 100. Additionally, in accordance with the present invention, the surgical cavity is further enlarged by the dilating element 112 substantially to the dimension 132 of the dilating element 112 and this latter enlargement or expansion of a surgical cavity constitutes two or three times greater enlargement than the enlargement of such a surgical cavity by the diameter 136 of the distal end of the cannula 100. This enhanced enlargement of

a surgical cavity eases further dissection of tissue as the cannula 100 is advanced along a target vessel, and facilitates subsequent manipulation of surgical tools within such surgical cavity.

[0011] Cannula 100 houses an endoscope 120 for viewing the surgical site and the target vessel through the transparent tip 104. The proximal end of endoscope 120 is attached to the proximal end of the cannula 100 by mating screw threads 128 at the proximal end of the cannula 100 and the proximal end of the endoscope 120 for fixedly positioning the endoscope 120 within the cannula 100. The proximal end of the endoscope 120 may include an eyepiece or camera attachment, or the like (not shown), and the distal end of endoscope 120 is positioned near the distal end of the cannula 100 in alignment with the tip 104 for visualization there through of tissue being bluntly dissected thereby as the cannula 100 is advanced along a target vessel.

[0012] Referring to Figure 3, tip 104 is made of a transparent material, such as polycarbonate plastic. Positioning endoscope 120 near the distal end of cannula 100 and in alignment with the transparent tip 104 therefore allows a surgeon to view objects forward of the cannula 100. This enables the surgeon to advance the cannula 100 along the path of a target vessel, and to view and thereby avoid avulsing any side branches. Tip 104 is tapered from the distal end thereof (that is blunted with a radius of about .045 inches) to the larger diameter of the proximal end of tip 104 that is approximately the diameter 136 of the distal end of the cannula 100. Tapering of the tip 104 over a taper length of about .500 to about .800 inches allows advancement of the cannula along the vessel without excessive force and injury to the vessel, as well as better visualization via the endoscope 120 of a target vessel through the tapered walls of the transparent tip 104.

[0013] In order to track the path of a target vessel effectively, the tapered wall of tip 104 is placed against the target vessel as the cannula 100 is advanced through connective tissue. The taper angle 116 of the tip 104 allows the target vessel to be seen more clearly and allows a length of vessel equivalent to the length of the taper of the tip 104 to be seen by the surgeon. In order to enable the tapered wall of tip 104 to lay against the target vessel, a spacer length 108 of cannula 100 between the dilating element 112 and the proximal end of tip 104 is provided to set the dilating element 112 back behind the taper angle 116 of the tapered wall of tip 104. This spacer length 108 of cannula 100 may have a diameter substantially equal to the outer diameter 136 of the distal end of the cannula 100. The spacer length prevents dilating element 112 from interfering with the contacting of the target vessel by the walls of the tapered tip 104, at taper angle 116. Without an intervening spacer length 108, the dilating element 112 more closely adjacent the tip 104 would prevent the tapered wall of tip 104 from contacting the target vessel within the taper angle 116, and this would increase the

force exerted on the target vessel during cannula advancement. In one embodiment, the distal end of dilating element 112 is 14-28 mm from the proximal end of the tip 104. Cannula 100 is preferably about 32-47 cm long, and tip 104 is preferably about 10-15 mm long.

[0014] Dilating element 112 is preferably formed of Teflon or polyurethane, or polycarbonate, or the like, to form a rigid shape which compresses or otherwise displaces tissue on the walls of the surgical cavity to form an enlarged surgical cavity. In an alternate embodiment, dilating element 112 comprises resilient foam which compresses in response to an applied external force. For example, pressure from inserting the dilating element 112 into a small incision may reduce the diameter of the dilating element 112 and prevent the dilating element 112 from causing further rupture or tearing of the incision. Since the tissue typically surrounding a target vessel such as the saphenous vein is soft fatty tissue, a foam dilating element 112 with sufficient resilience and rigidity may push back the fatty tissue and enlarge a surgical cavity adjacent the vessel. Dilating element 112 is preferably of oval shape to facilitate atraumatic expansion of the surrounding tissue following blunt dissection of the fatty tissue by the tapered tip 104. Of course, other shapes of dilating element 112 may be used that have maximum dimensions 132 greater than the dimension of the proximal end of tip 104.

[0015] In application, as shown in Figure 4, the surgeon incises 400 the skin of the patient and dissects 404 to expose the surface of the target vessel. The surgeon next places 408 the tapered wall of the transparent tip 104 on the surface of the vessel and advances 412 the tip 104 and cannula 100 under endoscopic visualization through the tip 104 along the path of the target vessel. Following dissection of the cavity along the vessel, the cannula 100 is removed 416, and a sealing trocar may be placed 420 in the incision for insufflating 424 the subcutaneous tunnel with gas under pressure to maintain the enlargement of the cavity. The vessel thus isolated is then harvested 428. A combined endoscopic and dissection instrument may be introduced through the sealing trocar to ligate and remove the target vessel for use, for example, as a coronary artery or peripheral vascular bypass graft. Alternatively, the isolated vessel may be left in place for surgical formation of an in-situ femoropopliteal or femoral-distal graft. Alternatively, following incision of the skin of the patient and dissection to expose the surface of the target vessel, gas insufflation may be initiated through a sealing trocar. The sealing trocar may be loaded onto the shaft of the cannula 100 prior to fixation of the dilating element 112 (if the outer dimension 132 of the dilating element 112 is greater than the inner diameter of the sealing trocar). The advancement 412 of the cannula 100 may then be conducted under gas insufflation, to improve visualization of the previously formed surgical cavity.

[0016] Figure 5a illustrates an embodiment of cannula 100 with a locking mechanism 150 for a detachable

dilating element 112 as shown in Figure 5b. Locking mechanism 150 includes a length of screw threads disposed on the surface or outer housing of the cannula 100 at a position near the distal end of the cannula that allows the locked dilating element 112 to be located in a position on the cannula 100 as described previously herein with reference to Figures 1-3.

[0017] Figure 5c illustrates a cross-section of the dilating element 112 having a mating lock or set of screw threads 162 which couples to locking mechanism 150 of Figure 5a. A bore hole 154 is formed along the horizontal axis of the dilating element 112, and the screw threads are disposed along a portion of the bore hole 154 as a mating lock 162. The dimension 158 of the bore hole 154 is wider than the diameter 136 of the cannula 100 but is small enough to ensure a tight coupling upon inserting the dilating element 112 into the locking mechanism 150. Thus, in this configuration, the dilating element 112 is locked onto the cannula 100 by rotating the grooved end of the dilating element 112 around the shaft of the cannula 100 until the distal end of the screw threads 150 on the cannula 100 contacts the unthreaded portion of the dilating element 112 in the bore hole 154. At this point, the dilating element 112 is locked.

[0018] Figure 6a illustrates an alternate embodiment of locking mechanism 150. A knob or protuberance is disposed on the surface of cannula 100 for mating with a corresponding groove 162, as shown in Figure 6c, in the dilating element 112. The groove 162 is formed to slide over knob 150 and mate therewith through partial rotation on the cannula 100 for locking the dilating element 112 of Figure 6b in place. In another embodiment, the locking mechanism 150 includes the groove in the surface of the cannula 100, and the dilating element 112 includes the protuberance disposed in the bore hole of the dilating element 112.

[0019] Figure 7 illustrates an exploded view of an embodiment of cannula 100 in which the tip 104 and the dilating element 112 are fixably coupled together as a unit, and are detachable from the distal end of cannula 100. This embodiment allows convenient change of dilating elements 112 by simply removing the dilating element 112 and tip 104 unit for replacement with an alternate dilating element 112 of different dimension and tip 104 unit. Threads 170 positioned at the distal end of the cannula 100 allows a threaded bore hole 154 (not shown) in the dilating element 112 or tip 104 unit to couple to the threaded shaft 170. This embodiment employing detachable or interchangeable dilating elements 112 allows the surgeon to control the size of the surgical cavity being dissected in tissue. This is accomplished by coupling dilating elements 112 of differing outer dimensions 132 to the cannula 100 which, in turn, enlarge the surgical cavity to sizes corresponding substantially to the dimensions 132 of the dilating elements 112. Different surgical cavities require different amounts of enlargement and therefore the surgeon may select

the amount of enlargement provided by the cannula 100 in a specific surgical cavity in accordance with the multiple dilating elements 112 that may be attached and utilized in succession in accordance with the described embodiments of the present invention.

[0020] The flow chart of Figure 8 illustrates a method for isolating a target vessel using the detachable dilating element 112. The surgeon incises 800 the skin and dissects 804 to expose the adventitial surface of the target vessel. The surgeon next places 808 the transparent tapered tip 104 on the adventitial surface of the vessel. The cannula 100 is advanced 812 under endoscopic visualization through the tip 104 until the target vessel is sufficiently isolated. The cannula 100 is removed 816 after establishing a subcutaneous tunnel or surgical cavity adjacent the target vessel which is more constricted than desirable, and therefore requires greater enlargement. The dilating element 112 is then removed and replaced 820 with a larger dilating element 112 and the cannula 100 is again advanced 824 through the tunnel until the surgical cavity is sufficiently dissected using interchangeable dilating elements 112 in a succession of progressively larger dimensions as necessary to attain the required amount of enlargement of the surgical cavity. The cannula 100 is removed 828 and a sealing trocar is placed 832 in the incision and the tunnel is insufflated 836 with gas under pressure to facilitate harvesting the vessel 840.

[0021] The cut-away side sectional views of Figures 9a and 9b illustrate an alternate embodiment of cannula 100 in which a slidable sheath 160 is employed to reduce the outer dimension 132 of the dilating element 112. In this embodiment, the dilating element 112 includes resiliently compressible foam, as described above. The sheath may be formed as a plastic tube which is slidably disposed on the cannula 100 and which has a distal end 168 and a proximal end 172.

[0022] Upon sliding or extending the sheath 160 in a distal direction, the distal end 168 of the sheath 160 encases the dilating element 112 and thereby compresses the dilating element 112 to a reduced dimension 132. Upon retracting the sheath 160 by sliding the sheath 160 in a proximal direction, the distal end 168 of the sheath 160 releases the dilating element 112 which resiliently expands to a larger dimension 132, as shown in Figure 9b. Thus, by compressing the dilating element 112 upon inserting the cannula 100 into an incision, rupture or tearing of the incision is minimized. When properly placed, the sheath 160 is retracted to enable resilient expansion of the dilating element 112, thereby to provide enlargement of the surgical cavity.

[0023] In application, as shown in the flow chart of Figure 10, the surgeon incises 1000 the skin and dissects 1004 to expose the adventitial surface of the target vessel. The surgeon next extends 1006 the sheath and places 1008 the transparent tapered tip 104 of the cannula 100, with the sheath extended, on the surface of the vessel. The sheath 160 retains the dilating element

112 in compressed configuration as the cannula is advanced 1012 until the ensheathed dilating element 112 is in selected position under the skin. The sheath 160 is retracted 1016 to allow the compressible dilating element 112 to expand. The cannula 100 is advanced 1020 under endoscopic visualization through the tip 104 until the target vessel is sufficiently isolated. The cannula 100 is removed 1024, and a sealing trocar is placed 1028 in the incision and the tunnel is insufflated 1032 with gas under pressure to facilitate harvesting 1036 the isolated vessel.

[0024] Therefore the method and apparatus of the present invention facilitate enlargement of a surgical cavity simultaneous with the advancement of the cannula 100 through the surgical cavity, without requiring intermittent manual manipulation of balloons or other similar devices. Additionally, the method and apparatus of the present invention provides for dilating the surgical cavity to different dimensions responsive to interchanging detachable dilating elements 112. Finally, the method and apparatus of the present invention provides for a dilating element 112 which has a compressible resilient dimension for insertion through an incision in a state of compressed dimension for minimizing rupture or tearing of the incision while still providing for enlargement of the surgical cavity in a state of resilient expansion.

Claims

1. A tissue dissector comprising:

an elongated cannula (100), having a proximal end and a distal end;
a tip (104) having tapered outer walls and being disposed on the distal end of the cannula for inserting into tissue; and
a dilating element (112) disposed on the cannula at a location thereon intermediate the distal and proximal ends thereof and having an outer dimension greater than the dimension of the distal end of the cannula for displacing tissue to form a surgical cavity therein.

2. The dissector of claim 1 in which the tip is transparent, and comprising:

an endoscope (120) disposed within the cannula, having a distal end positioned near the distal end of the cannula (100) and having a proximal end coupled to the proximal end of the cannula, the distal end of the endoscope being positioned near the tip (104) for providing a field of view through the tip.

3. The dissector of claim 1 or 2 in which the dilating element (112) is substantially of oval shape.

4. The dissector of one of the preceding claims wherein the cannula (100) further comprises:

a locking mechanism (150, 162), positioned near the distal end of the cannula (100) at a location recessed from the tip (104) disposed on the distal end of the cannula; and the dilating element (112) further comprises a mating lock (162) to mate with the locking mechanism for positioning the dilating element on the cannula at a location thereon recessed from the distal end thereof.

5. The dissector of claim 4 in which the locking mechanism (150, 162) further comprises a length of screw threads (150) positioned on the surface of the cannula, and the mating lock of the dilating element further comprises a threaded bore hole (154, 162) for fixably coupling the dilating element (112) to the length of screw threads.

6. The dissector of claim 4 in which the locking mechanism (150, 162) further comprises at least one protuberance (150) and the mating lock of the dilating element further comprises a mating slot (162) for fixably coupling the dilating element to the protuberance.

7. The dissector of one of the claims 4 to 6 for operation with selected ones of the population of dilating elements (112) of differing maximum dimensions for enlarging a surgical cavity to differing dimensions.

8. The dissector of one of the preceding claims wherein a spacer length (108) is disposed intermediate the tip (104) and the dilating element (112) having an outer dimension less than the outer dimension of the dilating element, for positioning the dilating element within an angle of the tapered outer walls of the tip to permit contact of the outer walls of the tip with a target vessel.

9. The dissector of one of the preceding claims in which the dilating element (112) is expansively resilient.

10. The dissector of claim 9, in which the dilating element is expansively resilient, and comprises:

a sheath (160) slidably positioned on the cannula, and having a distal end disposed upon the dilating element (112) in a first position and recessed from the dilating element in a second position, for reducing the outer dimension of the dilating element responsive to being in the first position and for allowing the expansion of the outer dimension of the dilating element

responsive to being in the second position

11. The dissector of claim 1 in which the tip (104) and the dilating element (112) form a single unit and a proximal end of the unit is configured to mate to the distal end of the cannula. 5

12. A method for enlarging a surgical cavity about a target vessel, using a tissue dissector (50) having a portion (112) thereof of expanded dimension and having a transparent tip (104) with tapered outer walls positioned at the distal end of the tissue dissector, the method comprising: 10

incising skin; 15
dissecting within the incision to expose a surface of the target vessel;
positioning a tapered outer wall of the transparent tip of the tissue dissector on the surface of the vessel; 20
advancing the tissue dissection under endoscopic visualization through the transparent tip; and
simultaneously expanding the surgical cavity in a lateral direction responsive to the portion of the tissue dissector of expanded dimension, as the tissue dissector is advanced. 25

13. The method of claim 12 comprising: 30

removing the tissue dissector from the expanded surgical cavity;
increasing the dimension of the portion of the tissue dissector of expanded dimension; and
re-inserting the tissue dissector into the surgical cavity for advancement therein to expand the dimension thereof in response to passage there through of portion of the tissue dissector of increased dimension. 35
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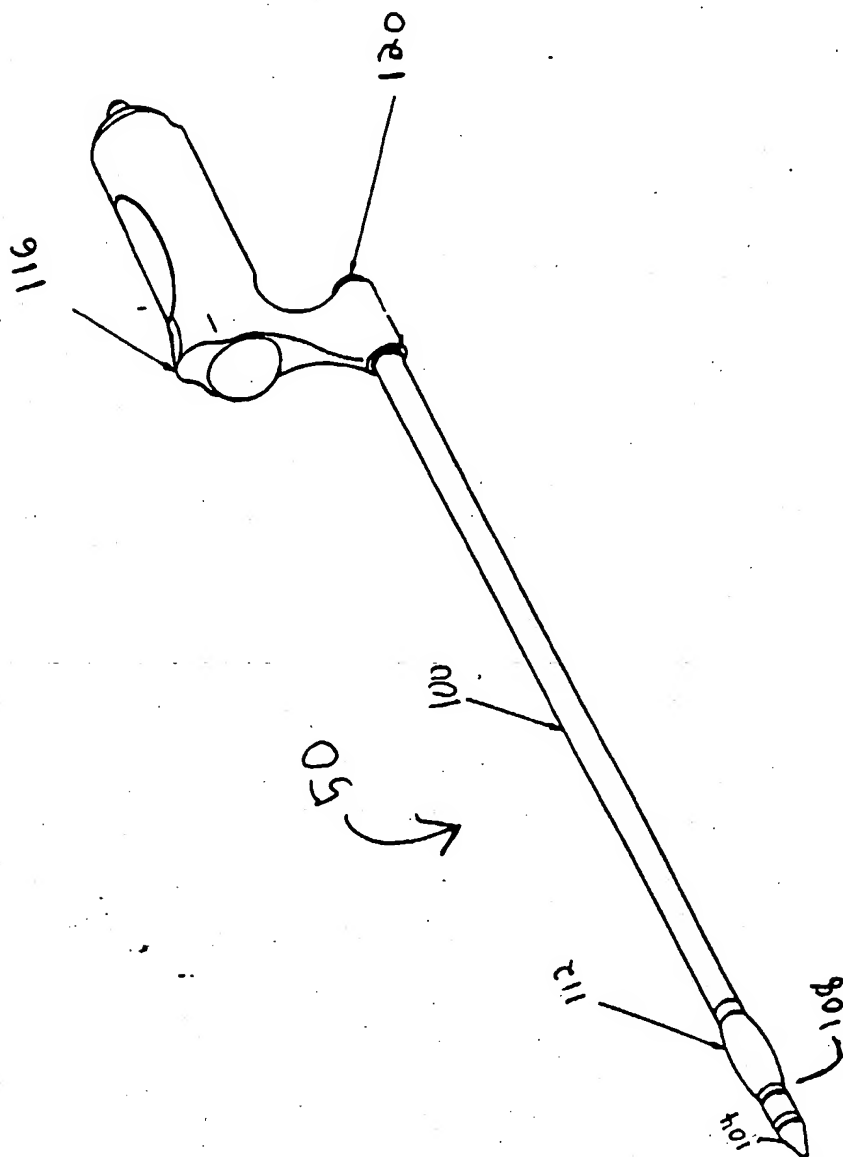


Figure 1

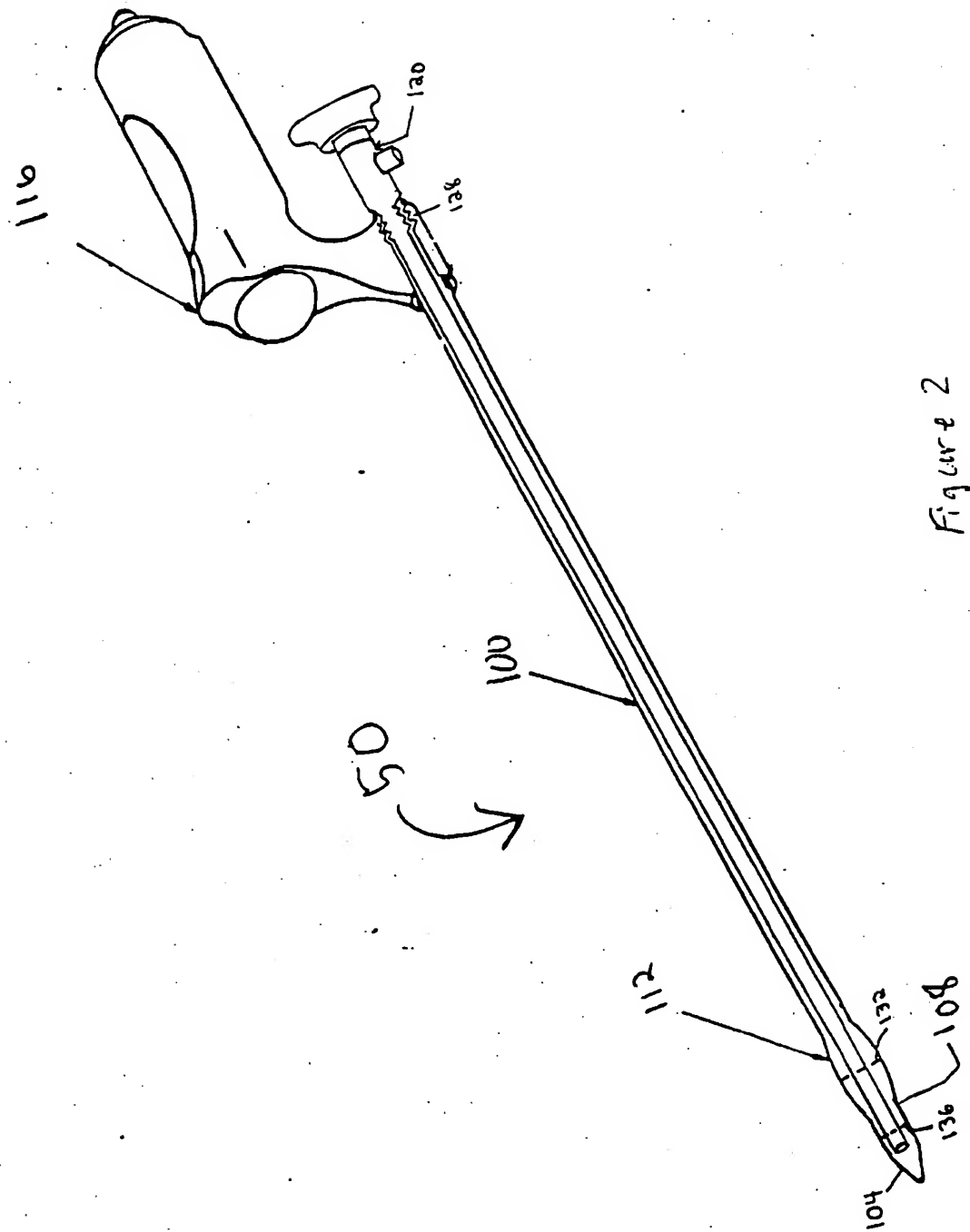


Figure 2

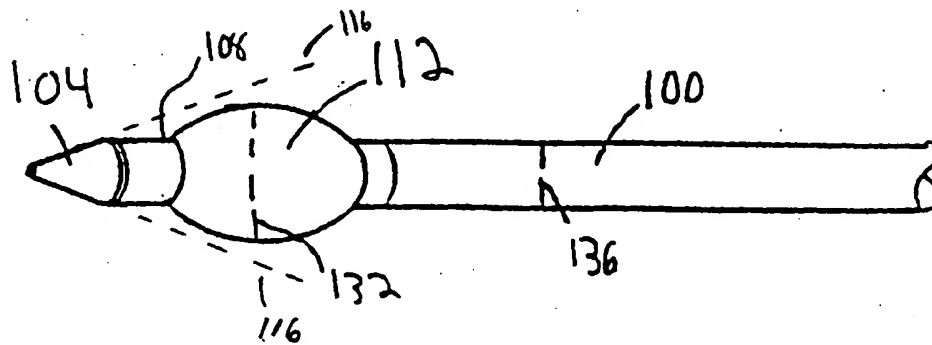


Figure 3

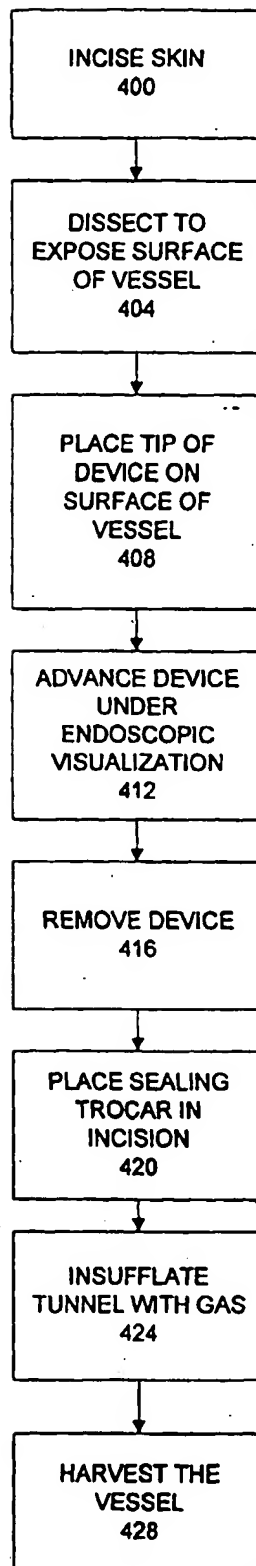


FIGURE 4

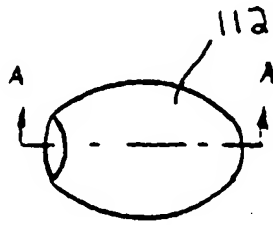


Figure 5b

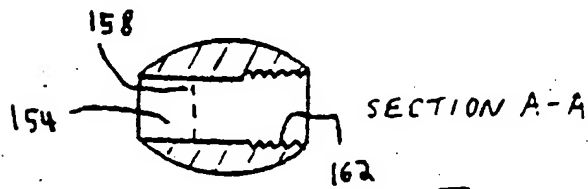


Figure 5c

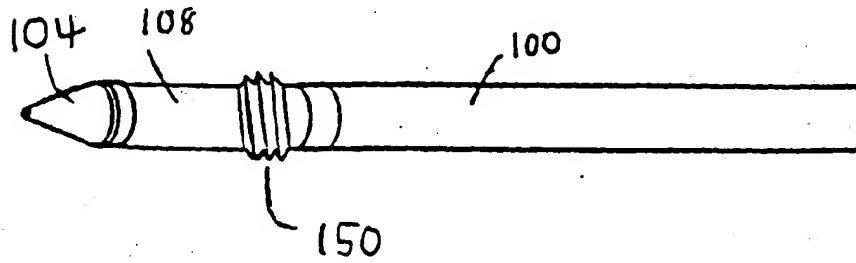


Figure 5a

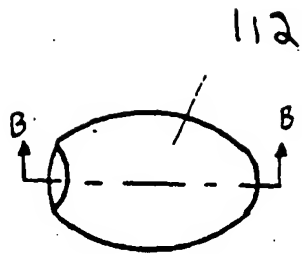


Figure 6b



Figure 6c

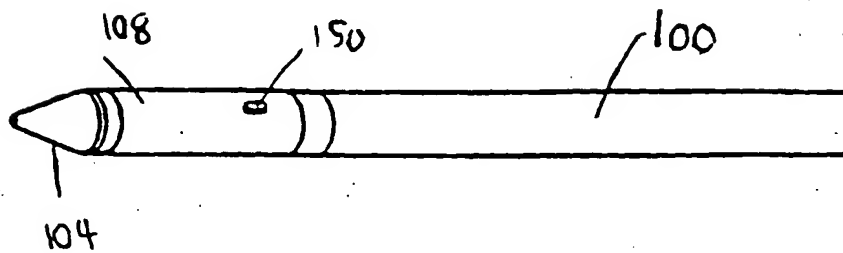


Figure 6a

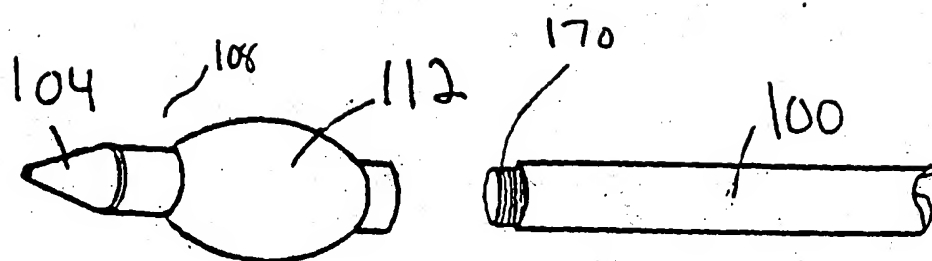


Figure 7

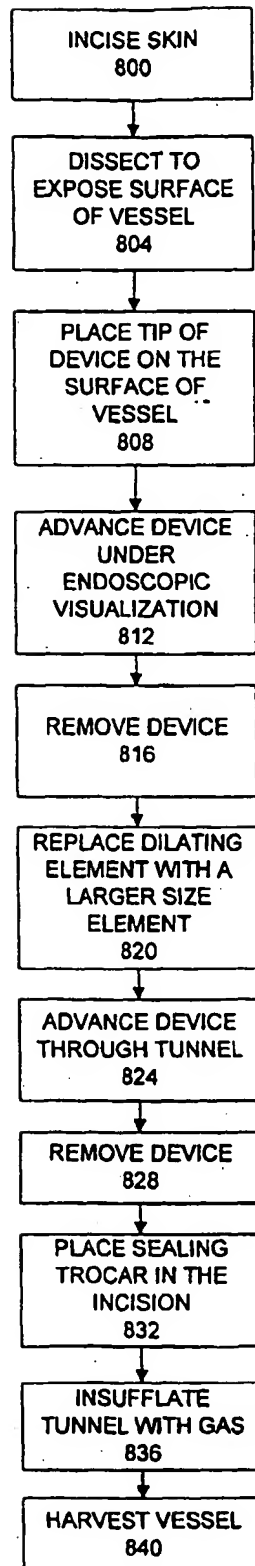


FIGURE 8

Figure 9a

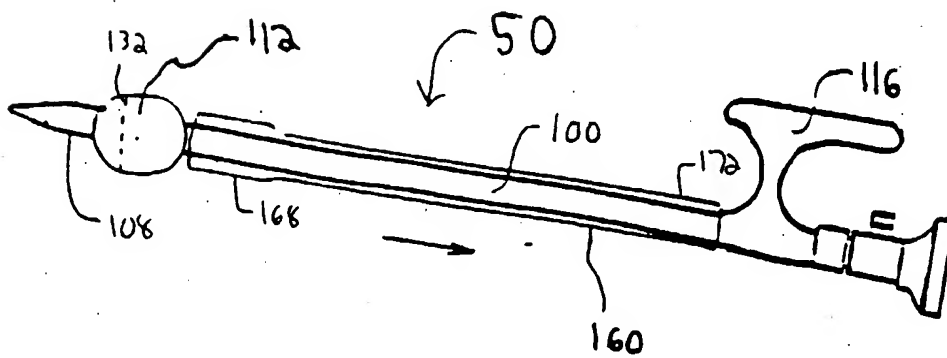
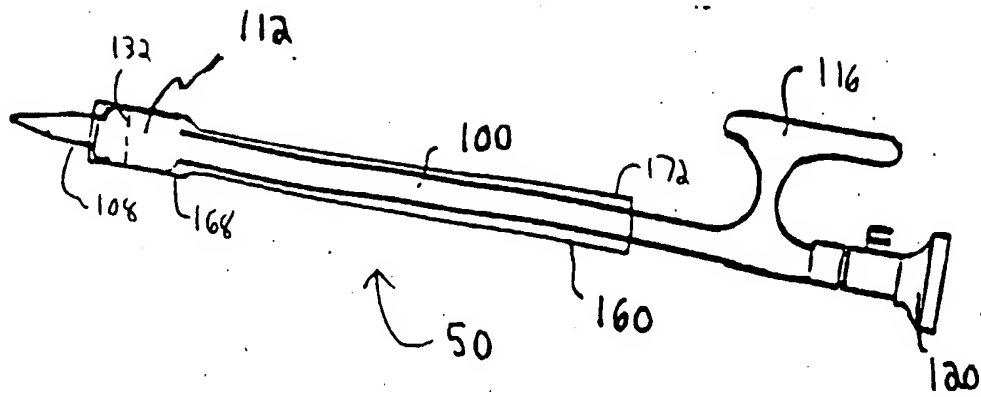


Figure 9b

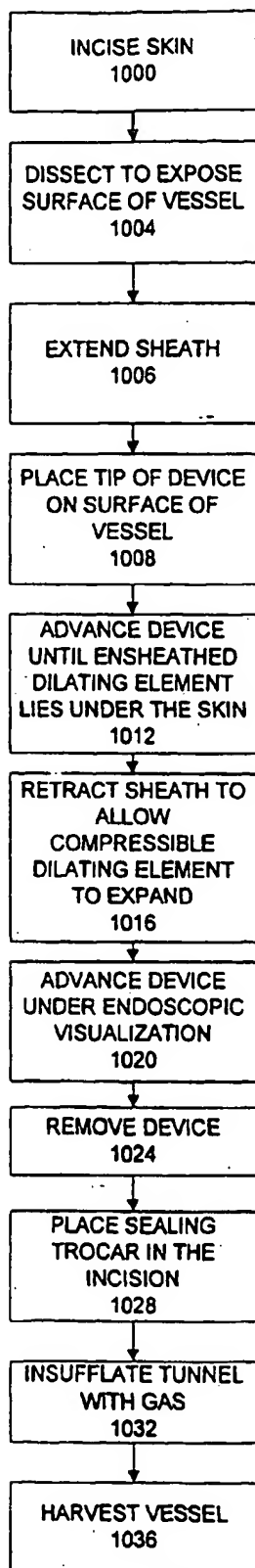


FIGURE 10

